## REMARKS

Claim 1 has been amended, claims 24, 29-30 and 35 have been cancelled without prejudice or disclaimer, and new claims 38-43 have been added. Claims 8, 10-12, 23, 27, 34 and 38-43 are currently pending.

Applicant reserves the right to pursue the subject matter of cancelled claims 24, 29-30 and 35 in a divisional application.

Claim 8 has been amended to clarify that step ii) is followed by steps iii) to v). Support for the amendment made to claim 8 is provided, for example, at page 14, line 8 to page 23, line 18, where it is shown that the first part of the correcting method of the present invention involves measuring the amount of blood substitute present in a specimen, followed by measuring an apparent amount of an analyte, and then removing the contribution of the blood substitute from the apparent amount of the analyte.

Claim 8 has also been amended to replace the term "a" preceding the term "blood substitute" in step i) with the term —said—, as antecedent support for the term "blood substitute" is present in the preamble of claim 8.

New claims 38-43 have been added, which are derived from currently pending claims 8, 10-12, 23, 27 and 34, and page 14, line 8 to page 24, line 6 of the description.

Page 1 of the specification has been amended to include a reference to earlier filed International Application No. PCT/CA97/00759 and U.S. Provisional Application No. 60/038,554, from which the present application claims priority.

## Summary of Interview with Examiner Soderquist on May 26, 2005

The disclosure of the Sagusa et al. reference was mainly discussed during the interview between Examiner Soderquist, Tim Clise, Applicant's U.S. agent or record, and Konrad Sechley, Applicant's Canadian agent. The Examiner maintained that the method of presently pending claim 8 was obvious having regard to Davis in view of Sagusa et al., Gimpel, Simon and Christenson, Leissing or Mullins.

Initially, the Examiner asserted that Figure 3 of Sagusa et al. illustrated a method for correcting a measured concentration of an analyte for three chromogenic interferents, namely, chyle, hemolysis and icteris, comprising a step of measuring the three interferents without the use of a colour-forming agent.

Later, the Examiner alleged that the method of previously pending claim 8 of the present application was similar to the method disclosed in Sagusa et al. in that the recited step of determining an initial concentration of an analyte (step iv)) could be carried out in the presence of a colour-forming agent and could precede the step of measuring an absorbance or reflectance of radiation (step ii), as previously pending claim 8 did not require that the recited steps be carried out in the order in which they were recited. Examiner Soderquist appeared to imply from his reasoning that the possibility of step iv) being carried out in the presence of a colour-forming agent and of step iv) preceding step ii) would result in the sample of step ii) including a colour-forming agent.

The Examiner was also of the opinion that the calibration algorithm recited in claim 8 was similar to the correction formulae disclosed in Sagusa et al. or to a chart that relates a concentration of extracellular hemoglobin to a particular color hue of a sample, as described in Davis.

Claim 24 and the associated dependent claims were not discussed in the telephone interview with the Examiner.

Following the interview, Examiner Soderquist left a telephone message with Tim Clise, suggesting that amendment of claim 8 to clarify that the step of measuring (step ii)) is followed by step iv) may possibly overcome the outstanding obviousness rejection against this claim, provided that support for this amendment could be shown in the originally filed specification.

## Claim Rejections–35 USC 103

Examiner has rejected claims 8, 10-12, 23-24, 27, 29-30 and 34-35 under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Sagusa, Gimpel, Simon and Christenson, Leissing or Mullins.

More particularly, Examiner has alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include substances such as blood substitutes disclosed by Christenson, Leissing or Mullins as interfering substances into the correction method of Davis.

Examiner's rejection of claims 24, 29-30 and 35 has been rendered moot by the cancellation of these claims. Applicant respectfully traverses Examiner's rejection of claims 8, 10-12, 23, 27 and 34 for the reasons set forth below.

Davis discloses a method of estimating a change in the concentration of an analyte in a whole-blood sample due to the hemolysis of red blood cells, for example separating a plasma fraction from the whole blood sample, estimating the quantity of extracellular hemoglobin in the plasma fraction, estimating a change in the analyte concentration in the sample due to the hemolysis of whole blood cells, and adjusting the apparent concentration of the analyte to account for the proportion of same which is due to the hemolysis of red blood cells (column 6, lines 3-16; column 8, lines 40-56).

Sagusa teaches a colorimetric method for measuring components in a sample in the presence of interfering chromogens. In the method disclosed in Sagusa, a color former is added to blood samples for colouring, and measurements for specific components are determined based on the light absorbance caused by the colouring. The measurements for specific components are corrected by the degree of chyle, degree of hemolysis and degree of icterus, which are determined at different wavelengths.

Neither Davis nor Sagusa, nor any one of the other cited references specifically teaches or suggests, individually or in combination, the presently claimed method of determining a corrected concentration of an analyte in a specimen comprising **both** a blood substitute interferent and a non-blood substitute interferent, which comprises measuring an absorbance or reflectance of radiation of a specimen in the absence of any reaction step that generates a chromophore within the specimen and determining the concentrations of the blood substitute interferent and the non-blood substitute interferent (steps ii) and iii)), **followed by** a step of determining an initial concentration of the analyte in the specimen with an analyzer and a step of correcting the initial concentration of the analyte. More particularly, neither Davis, Sagusa nor any of the other cited references teaches or suggests individually or in combination, a method that includes a step of removing the contribution of **both** a blood substitute interferent and a non-blood substitute interferent from an initially measured concentration (apparent concentration) of an analyte to produce a corrected concentration of the analyte, as defined in presently amended claim 8.

In particular, it is respectfully pointed out that unlike the method of Sagusa, the presently claimed method of claim 8 does not require the generation of a chromophore within a specimen prior to the absorbance or reflectance of the specimen being measured. Although the Examiner appeared to indicate initially in the telephone conversation of May 26, 2005, which was summarized above, that Figure 3 of Sagusa et al. is illustrative of a method of correcting the concentration of an analyte, comprising a step of measuring interferents in the absence of a colour-forming agent, it is respectfully submitted that this conclusion is not correct. Rather, Figure 3 of Sagusa et al. shows the absorbance spectra of chyle, hemolysis and icterus interferents of reference solutions of these interferents for illustrative purposes only, and does not suggest that the disclosed **colorimetric** method of Sagusa et al. does not require the addition of a colour-forming agent to be added initially to the specimen being analyzed.

With respect to new claims 38-43, neither Davis nor Sagusa, nor any one of the other cited references specifically teaches or suggests the presently claimed method of determining a corrected concentration of an analyte in a specimen comprising a blood substitute interferent, which comprises measuring an absorbance or reflectance of radiation of a specimen in the

absence of any reaction step that generates a chromophore within the specimen and determining the concentration of the blood substitute interferent (steps ii) and iii)), **followed by** a step of determining an initial concentration of the analyte in the specimen with an analyzer and a step of correcting the initial concentration of the analyte.

Examiner is respectfully requested to withdraw the rejection to claims 8, 10-12, 23-24, 27, 29-30 and 34-35 under Section 35 U.S.C. § 103(a).

## CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 349-9587 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date 6 June '05 (Monday)

By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop ~~AP~~ RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 6th day of June, 2005.

PATRICIA A. HULTMAN

Name

Signature